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Richard E. Hill, Jr.
Center for Veterinary Biologics
510 South 17th Street
Suite 104
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JAN 10 2003

In re Application for Patent Term Extension
U.S. Patent No. 5,275,813

Dear Mr. Hill, Jr.:

This is in reply to your letter dated September 24, 2002. To assist the Office in proper routing of your letters, please address them to:

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
Washington DC 20231

The letter dated September 24, 2002 is understood to conclude that the regulatory review period defined in 35 U.S.C. 156(g)(5)(B)(ii) for the veterinary biologic product Fel-O-Vax® FIV vaccine (Feline Immunodeficiency Virus Vaccine, Killed Virus) began on May 4, 1998, with the submission of the application for United States Veterinary Biological Product License, and ended with issuance of such license, on March 14, 2002. The determination does not specify "the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective." (See 35 U.S.C. 156(g)(5)B)(i).) From the application for patent term extension, specifically page 5 of the application, it seems that applicant is arguing that such date is August 28, 1991. If the United States Department of Agriculture (USDA) has concluded that there was no regulatory review period as defined in 35 U.S.C. 156(g)(5)(B)(i) because there was no specific authority from USDA to prepare the experimental biologic, then it would be helpful for the regulatory review period determination that is published in the Federal Register to specify that there was none, and the basis for this conclusion.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone), (703)872-9411 (facsimile), or karin.ferriter@uspto.gov (e-mail).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Kevin L. Bastian
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RE: Fel-O-Vax® FIV vaccine